

## **Remarks**

### **I. Summary of the Office Action**

In the Office Action mailed April 9, 2010, the Office rejected claims 1, 2, 4-11, and 13 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kotula (WO 97/42878), while claims 12 and 15 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kotula in view of Freudenthal (WO 01/49785) and further in view of Solymar (US Pat. App. 2003/0149463) and claim 16 was rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kotula in view of Chanduszko (U.S. Pat. App. 2005/0043759)

Claims 1-2, 4-13, and 15-23 are currently pending in the application. Of these claims, claim 1 is in independent format, and the rest are in dependent format. Applicants submit that the claims, as they stand, distinguish over the cited art.

### **II. Status of the Claims**

Applicants have amended claim 1 to correct a typographical error.

Applicants have also added dependent claim 17, which recites that “the elongate members are wires or threads,” and dependent claim 18, which recites that “the elongate members are only joined together by the first and second holders and by the first and second occluding bodies.” These new claims find support in the Applicant’s published application at paragraphs [0026-0028].

In addition, Applicants have added independent claim 19 and claims 20-23, which depend therefrom. These claims find support throughout the specification, for example, in Figures 1-6 and paragraphs [0026-0029, 0035-0036].

No new matter has been added by these amendments.

### III. Response to Rejection Under 35 U.S.C. § 102(b)

Claims 1, 2, 4-11, and 13 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kotula. According to MPEP § 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.' *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). . . . The identical invention must be shown in as complete detail as is contained in the . . . claim.' *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)." At a minimum, Kotula does not disclose "a plurality of thin elongate members each having a first end and a second end," "a first occluding body being attached to the elongate members," "at least one fixation structure being fixable," or "one second occluding body being attached to the elongate members," as recited in independent claim 1.

At best, Kotula discloses an occluder consisting of a metal braided fabric that is "generally tubular." *Kotula*, pp. 6, lines 6-9; p. 7, line 30 to p. 8, line 1; Figures 1A and 1B. This fabric is placed in a mold and heat treated to substantially set a desired shape (i.e. providing shape memory), so that it will tend to assume the preferred configuration of the mold unless constrained from doing so. *Id.* at p. 7, lines 3-18. Accordingly, "[i]n instances where the device is improperly deployed on a first try, the device 300 may be recovered by pulling the delivery device 312 proximally, thereby retracting the device 300 back into the delivery catheter 314 prior to a second attempt at positioning the device 300 relative to the defect." *Id.* at p. 29, line 30 to p. 30, line 2.

Kotula's tubular braided fabric is a criss-crossing mesh. Comparing Kotula's Figures 1A and 1B with Applicant's Figure 1, as shown below, it is clear that Kotula does not teach or

disclose “a plurality of thin elongate members each having a first end and a second end,” as recited in claim 1.



Fig. 1A

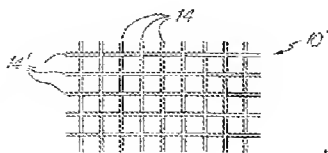


Fig. 1B

Kotula Figs 1A-B

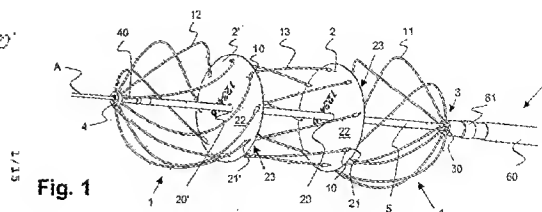


Fig. 1

Applicant's Fig. 1

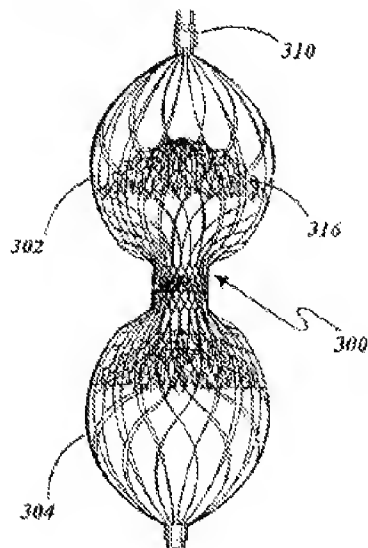
And Kotula's disclosure of shape memory and the ability to re-deploy Kotula's occluder teaches away from the claim limitation of “at least one fixation structure being fixable.” Specifically, the shape memory of Kotula's occluder allows it to remain in the deployed position and this shape memory is overcome by stretching it into an elongated position. *Id.* at p. 29, lines 14-15, 24-27; p. 29, line 30 to p. 30, line 2. Alternatively, Applicant states that “[o]ne way to keep the implant in this second state, i.e. *to fix the elongate members 1* in their twisted position, is to attach the two holders 3, 4 to each other. In this embodiment, *the two holders 3, 4 . . . comprise a locking mechanism . . .*” *Applicants' Pub. App.*, ¶ [0038] (emphasis added).

Moreover, in the relaxed unstretched state, Kotula's occluder has two disks 302, 304 aligned in spaced relation and linked together by a short cylinder 306. *Kotula*, p. 27, lines 15-17. And Kotula's occluder operates through the formation of thrombi in and on the device that eventually results in an occluding body. *Id.* at p. 20, lines 29-30. “The device can contain polyester fibers 316 (see Figures 15 and 18)” disposed within the space of the disks 302, 304 but not attached to the strands of the metal fabric. *Id.* at p. 29, lines 24-27. These polyester fibers 316 act as a thrombogenic agent that speeds up the thrombosis but the polyester fiber 316 does not act as an occluding body on its own. *Id.* at p. 20, line 30 to p. 21, line 2.

Note the obvious contrast between Kotula's free-floating polyester fibers 316, shown in

Figure 18 below, and an embodiment of Applicant's claimed first and second occluding bodies 2, 2' that are attached to the elongate members, shown in Figure 3 below.

Fig.18



Kotula's Fig. 18

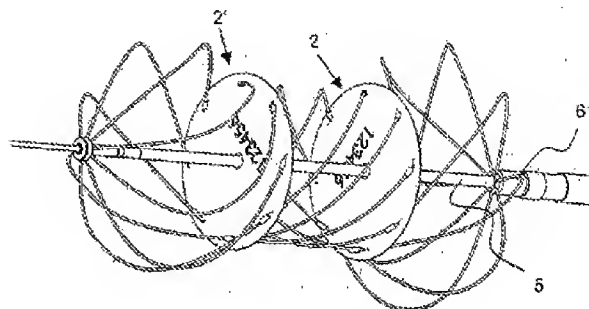


Fig. 3

Applicant's Figure 3

Kotula's free-floating polyester fibers 316 cannot be considered an occluding body that closes an internal passage. And Kotula's disclosure underscores this point by specifically stating that "thrombi will occlude the [device]." *Id.* at p. 20, line 30. As such, Kotula does not disclose either "a first occluding body being attached to the elongate members" or "one second occluding body being attached to the elongate members," as recited in independent claim 1.

Accordingly, Kotula's disclosure is deficient, failing to disclose at least "a plurality of thin elongate members each having a first end and a second end," "a first occluding body being attached to the elongate members," "at least one fixation structure being fixable," or "one second occluding body being attached to the elongate members," as recited in independent claim 1. As claims 2, 4-11, 13, and 15-18 are dependent upon Claim 1, those claims are also not anticipated. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection based on 35 U.S.C. § 102(b).

#### IV. Response to Rejection of Claims 12 and 15 Under 35 U.S.C. § 103(a)

Claims 12 and 15 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kotula in view of Freudenthal and in further view of Solymar. Claim 12 is dependent on claim 1, and Applicants submit that the deficiencies in the Kotula reference are not cured by the teachings of the Freudenthal and Solymar references. The Examiner alleges that it would have been obvious to modify Kotula's implant "to include the membrane of Freudenthal for a sealing effect, and elongate members extending through the occluding body for the purpose of better securing the occluding member to the elongate members." *Office Action*, p. 5. But Kotula's tubular braided fabric would not function with Freudenthal's membrane and Solymar's elongate members extending through holes of an occluding body, because Kotula does not have elongate members. Instead, Kotula discloses a tubular braided fabric that would preclude the holes in Solymar's occluding member from mating with Kotula's device. To underscore the inoperability of this combination, see Kotula's braided fabric and Solymar's occluding member below.

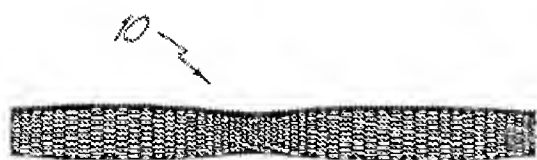
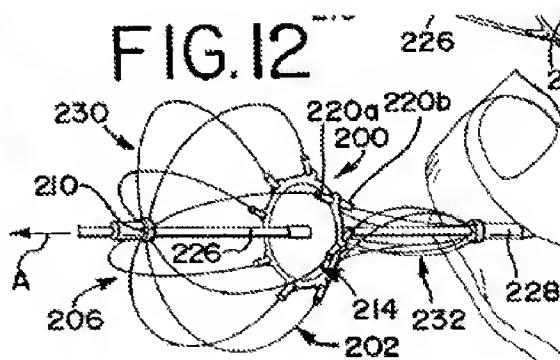


Fig. 1A

Kotula Fig. 1B



Solymar Fig. 12

As shown, logistically, the holes in Solymar's occluding member are not designed to receive Kotula's braided fabric.

Accordingly, Applicants submit that claim 12 is allowable. And since claim 15 is dependent on claim 12 it likewise is not rendered obvious. Thus, Applicants respectfully request

reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

**V. Response to Rejection of Claim 16 Under 35 U.S.C. § 103(a)**

Claim 16 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kotula in view of Chanduszko. Claim 16 is dependent on claim 1, and Applicant submits that the deficiencies in the Kotula reference are not cured by the teachings of the Chanduszko reference. Specifically, Chanduszko discloses an occluder formed from a tube that is cut to produce struts in each side. *Chanduszko*, Abstract. A middle tube 22 with no slits is disposed between end 39 and tip 44, which contains Chanduszko's locking mechanism 191. *Id.* at ¶ [0066].

There is no motivation or suggestion in the art to combine Chanduszko's locking mechanism with Kotula's device. And Kotula's disclosure actually teaches away from this combination by disclosing that Kotula's device is held in place by "resiliently return[ing] to its predefined expanded disk-like shape." *Kotula*, p. 29, lines 26-27. So adding a locking mechanism to Kotula's device would serve no purpose. Further, Chanduszko's locking mechanism is activated through a "pulling force." *Chanduszko*, ¶ [0066]. But there is no force applied during the delivery of Kotula's device, which is self-activating.

Therefore, Applicant submits that claim 16 is allowable and Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

**VI. Discussion of New Claims 19-23**

Claims 19-23 are in condition for allowance for the same or similar reasons that the foregoing claims are not anticipated or rendered obvious by the cited references. For example, at a minimum, none of the references of record disclose the following limitations of claim 19: (a) a plurality of thin stiff elongate members each having a first end and a second end, (b) a first expansible occluding body being attached to the elongate members at a point between the first

and second holders, (c) a second expansible occluding body being attached to the elongate members at another point between the first and second holders and spaced from the first occluding body.

Likewise, none of the references of record disclose claim 20's limitation that the first fixation structure is formed between the first occluding body and the first holder and the second fixation structure is formed between the second occluding body and the second holder.

Similarly, none of the references of record disclose claim 21's limitation that the elongate members have first portions being arranged between the first holder and the first occluding body, second portions being arranged between the second holder and the second occluding body and third portions being arranged between the first and second occluding body, with the first, second and third portions of the elongate members being respectively located in spaced apart relation by the occluding bodies until forming the fixation structures.

And none of the references of record disclose claim 21's "the third portions arranged between the first and second occluding bodies twist into a compressed shape between the first and second occluding bodies in the second state, the first portions forming the first fixation structure and the second portions forming the second fixation structure.

Lastly, none of the references of record disclose claim 23's "compressed shape of the third portions is contained within the area of the occluding bodies.

## **VII. Conclusion**

In view of the foregoing, Applicant submits that all of the pending claims are in condition for allowance. Therefore, Applicant respectfully requests favorable reconsideration and allowance of all the claims (1-2, 4-13, and 15-23). If the Examiner would like to discuss any aspect of this case, the Examiner is invited to telephone the undersigned at 312-913-0001.

Respectfully submitted,

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Date: July 9, 2010

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